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| APPLICATION NO.             | FILING DATE                            | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|-----------------------------|--|----------------------|-----------------------|------------------|
| 10/590,530                  | 05/16/2007                             | Clifford J. Hawkins  | 007193-26 US          | 6797             |
|                             | 7590 12/18/2007<br>JUM LAW FIRM, P. C. |                      | EXAMINER              |                  |
| 685 BRIGGS S                |  |                      | ANDERSON, HEATHER L   |                  |
| PO BOX 929<br>ERIE, CO 8051 |  |                      | ART UNIT PAPER NUMBER |                  |
| , <b></b>                   | -                                      |                      | 1655                  |                  |
|                             |  |                      |                       |                  |
|                             |  |                      | MAIL DATE             | DELIVERY MODE    |
|                             | •                                      |                      | 12/18/2007            | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| •  |  | Application No.  | Applicant(s)  |  |  |  |  |
|--|--|--|---|--|--|--|--|
| Office Action Summary  |  | 10/590,530   | HAWKINS, CLIFFORD J.  |  |  |  |  |
|  |  | Examiner   | Art Unit  |  |  |  |  |
|  |  | Heather Anderson   | 1655  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |  |   |  |  |  |  |
|  | ORTENED STATUTORY PERIOD FOR REPLY   | / IS SET TO EVOIDE 4 MONTH(  | S) OR THIRTY (30) DAYS  |  |  |  |  |
| WHIC<br>- Exter<br>after<br>- If NO<br>- Failu<br>Any  | CHEVER IS LONGER, FROM THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE. THE MAILING DATE IN THE MAILING DATE IN THE MAILING DATE. T | ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tim  17 iii apply and will expire SIX (6) MONTHS from  18 cause the application to become AB ANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C.§ 133). |  |  |  |  |
| Status   |  |  |   |  |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 24 Au  |  |   |  |  |  |  |
| • —  | This action is FINAL. 2b) ☐ This action is non-final.  |  |   |  |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  |  |   |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |  |   |  |  |  |  |
| Disposit   | ion of Claims  |  |   |  |  |  |  |
| · •  | 4)⊠ Claim(s) <u>35-55</u> is/are pending in the application.   |  |   |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.   |  |   |  |  |  |  |
| 5) Claim(s) is/are allowed.  |  |  |   |  |  |  |  |
| -  | 6) Claim(s) is/are rejected.   |  |   |  |  |  |  |
| •  | Claim(s) is/are objected to.  Claim(s) 35-55 are subject to restriction and/or   | election requirement.  |   |  |  |  |  |
| 8) Claim(s) 35-55 are subject to restriction and/or election requirement.  |  |  |   |  |  |  |  |
| Applicat   | ion Papers   |  |   |  |  |  |  |
| <i>,</i> —   | The specification is objected to by the Examine  |  | <b></b> .   |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |  |  |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |  |   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |  |  |   |  |  |  |  |
| Priority   | under 35 U.S.C. § 119  |  |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:   |  |  |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |  |  |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No   |  |  |   |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage  |  |  |   |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |  |  |   |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |  |  |   |  |  |  |  |
|  |  |  |   |  |  |  |  |
|  |  |  |   |  |  |  |  |
| Attachmer  |  | Λ [] Interitor A   | · (DTO 442)   |  |  |  |  |
| , <del></del>  | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)  | 4) Interview Summary<br>Paper No(s)/Mail D   | ate   |  |  |  |  |
| 3) 🔲 Infor   | mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date  | 5)  Notice of Informal F<br>6)  Other:   | Patent Application  |  |  |  |  |

Application/Control Number: 10/590,530

Art Unit: 1655

## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 35-38, drawn to a method comprising administering to a food zingibain to affect food intolerance in a subject.

Group II, claim(s) 39, drawn to a method comprising utilizing zingibain in the production of alcohol from cereal in order to increase the efficiency of said production of said alcohol from said cereal.

Group III, claim(s) 40-41, drawn to a method of preparing a bakery product with cleaved gluten comprising using zingibain.

Group IV, claim(s) 42-45, drawn to a food comprising an amount of zingibain to increase the percentage water content.

Group V, claim(s) 46-51, drawn to a food comprising an amount of zingibain to affect food intolerance in a subject.

Group VI, claim(s) 52-53, drawn to a method comprising administering zingibain for the treatment of a condition.

Group VII, claim(s) 54, drawn to a method comprising administering zingibain to a meat product to cleave prion proteins.

Group VIII, claim(s) 55, drawn to a method comprising utilizing zingibain in cell harvesting to cleave fibrinogen.

Application/Control Number: 10/590,530

Art Unit: 1655

The inventions listed as Groups I - VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared or corresponding technical feature is a contribution over the prior art.

The common technical feature among Groups I - VIII is zingibain. Lee at al. (Journal of Food Science, 1986, cited in Applicant's IDS) teach the use of zingibain as a meat tenderizer (see, e.g., the abstract and the entire document). Therefore the technical feature is not a contribution over the art, and the claims lack unity.

Furthermore, it is noted that in the International preliminary Report on

Patentability, that the Officer found that "requirement of unity of invention is not

complied with, " and stated that zingibain and the various uses thereof is known in the

prior art.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Application/Control Number: 10/590,530

Art Unit: 1655

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

## Rejoinder Practice

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Application/Control Number: 10/590,530 Page 5

Art Unit: 1655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather L. Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA

TERRY MCKELVEY, PH.D. SUPERVISORY PATENT EXAMINER